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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/532,114	06/23/2006	Francois Schutze	032013-119	9051

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EXAMINER	
SPIVACK, PHYLLIS G	
ART UNIT	PAPER NUMBER
1614	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/532,114	SCHUTZE ET AL.	
	Examiner	Art Unit	
	Phyllis G. Spivack	1614	

– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 December 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6 and 9-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6, 9-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Applicants' Amendment filed December 7, 2007 is acknowledged. Claims 1-6 and 9-18 remain under consideration.

In the last Office Action claims 1-6 and 9-18 were rejected under 35 U.S.C. 103(a) as being unpatentable over Brulls, M., U.S. Patent 6,730,685, in view of Facts & Comparisons. It was asserted Brulls teaches pharmaceutical compositions that are combinations of tenatoprazole and H_2-blockers, such as ranitidine. See column 7, lines 22-26. Tenatoprazole is exemplified as a compound of Formula I at the top of column 12. Brulls' teaching is drawn to treatment of diseases relating to gastric hyperacidity, such as gastric and duodenal ulcers and reflux esophagitis, as required by instant claims 17 and 18. See columns 6-7 under Use of the Invention. A dosage range for tenatoprazole is taught to be 1-100 mg once or twice a day (column 7, lines 14-15). Both oral and parenteral administration is disclosed in column 3, lines 1-8. As required by instant claim 5, sodium or potassium salts are disclosed in claims 4 and 5. As required by instant claims 4, 6, 10 and 11, Facts & Comparisons teaches an oral dose of the H_2-blocker ranitidine to be 150 mg and a parenteral dose to be 50 mg.

Applicants argue the combination of tenatoprazole and a histamine H2-receptor antagonist yields unexpected and superior results compared to the administration of other proton pump inhibitors and other histamine H2-receptor antagonists, used alone or in combination. Further, Applicants urge Brulls is not specifically directed to tenatoprazole but rather to a general description of all proton pump inhibitors and Facts & Comparisons merely relates to ranitidine, as well as information on dosing, pharmacokinetics and indications of use.

Those proton pump inhibitors contemplated in Brulls' disclosure are clearly set forth in Columns 11 and 12. Tenatoprazole is the first compound at the top of column 12. Formulations

comprising a combination of a proton pump inhibitor and a H_2-blocker are clearly encompassed in Brulls' disclosure. See column 7, lines 22-26. No unexpected results are shown in Table 2 on page 8 of the instant specification following the administration of a capsule formulation having tenatoprazole 20 mg and ranitidine 200 mg. Applicants have not shown this combination of tenatoprazole and ranitidine to be markedly superior to the control of gastric acidity compared to the administration of each component alone. Improvement of symptoms is entirely expected.

A reference may be applied not only for what it expressly teaches by direct anticipation, but also for what one of ordinary skill in the art might reasonably infer from the teachings. See *In re Opprecht*, 12 USPQ 2d, 1235, 1236 (Fed. Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA 1976). In light of the foregoing, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 U.S.C. 103(a).

Facts & Comparisons is applied in the present rejection specifically to show information on dosing, pharmacokinetics and indications of use.

Further, it is not inventive to discover an optimum or workable range by routine experimentation when general conditions of a claim are disclosed in the prior art. See *In re Aller*, 105 USPQ 233,235 (CCPA 1955) and MPEP 2144.05(II). The currently claimed specific weight ratio ranges are not seen to be inconsistent with ranges that would have been determined by the skilled artisan.

Applicants' arguments are not found persuasive. The rejection of record of claims 1-6 and 9-18 under 35 U.S.C. 103 is maintained.

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this Final Action is set to expire THREE MONTHS from the mailing date of this Action. In the event a first reply is filed within TWO MONTHS of the mailing date of this Final Action and the Advisory Action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the Advisory Action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the Advisory Action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this Final Action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Phyllis G. Spivack whose telephone number is 571-272-0585. The Examiner can normally be reached from 10:30 to 7 PM.

If attempts to reach the Examiner by telephone are unsuccessful after one business day, the Examiner's supervisor, Ardin Marschel, can be reached 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Phyllis G. Spivack/
Primary Examiner, Art Unit 1614

March 8, 2008